

**IN THE CLAIMS:**

Please substitute the following listing of claims for the previous listing of claims:

1-52. (Cancelled)

53. (Previously presented) A method for aerosolizing a pharmaceutical formulation, the method comprising:

providing a valve within an airway leading to the lungs to prevent respiratory gases from flowing to the lungs when a user attempts to inhale, and then abruptly permitting respiratory gases to flow to the lungs by opening the valve when a threshold actuating vacuum caused by the attempted inhalation is exceeded,

providing a flow regulator within the airway, wherein the flow regulator varies the flow resistance through the airway to control the flow of respiratory gases; and

using the flow of respiratory gases to extract a pharmaceutical formulation from a receptacle and to place the pharmaceutical formulation within the flow of respiratory gases to form an aerosol.

54. (Previously presented) A method as in claim 53 wherein the threshold actuating vacuum is in a range from about 20 cm H<sub>2</sub>O to about 60 cm H<sub>2</sub>O.

55. (Previously presented) A method as in claim 53 wherein the flow regulator limits the flow of respiratory gases to the lungs is to a rate that is less than a certain rate.

56. (Previously presented) A method as in claim 55 wherein the certain rate is about 15 L/min.

57. (Previously presented) A method as in claim 53 wherein the flow regulator regulates the size of the airway leading to the lungs.

58. (Previously presented) A method as in claim 57 wherein the flow regulator comprises an elastomeric duckbill valve.

59. (Previously presented) A method as in claim 53 wherein the valve and the flow regulator are provided in series.

60. (Previously presented) A method as in claim 53 wherein the airway includes a parallel flow arrangement.

61-68. (Cancelled)

69. (New) An aerosolization system comprising:  
a receptacle that holds a pharmaceutical formulation;  
a housing defining an airway;  
a coupling mechanism adapted to couple the receptacle to the airway;  
a flow regulator that regulates flow through the airway;  
a deagglomeration mechanism that deagglomerates aerosolized powder;  
and  
a mouthpiece,  
wherein the pharmaceutical formulation may be aerosolized to flow through the airway and out through the mouthpiece to a user.

70. (New) An aerosolization system as in claim 69 wherein the flow regulator regulates the flow through the airway by regulating the size of the airway.

71. (New) An aerosolization system as in claim 69 wherein the receptacle is downstream of the flow regulator.

72. (New) An aerosolization system as in claim 69 wherein the flow regulator comprises a valve comprising an adjustable size orifice to regulate flow.

73. (New) An aerosolization system as in claim 69 wherein the flow regulator comprises an adjustable restriction mechanism to vary flow rate.

74. (New) An aerosolization system as in claim 69 wherein the flow regulator comprises a shuttle that limits flow rate through the airway.

75. (New) An aerosolization system as in claim 74 wherein the shuttle is biased.

76. (New) An aerosolization system as in claim 74 wherein the shuttle is spring-biased.

77. (New) An aerosolization system as in claim 74 wherein the shuttle interacts with a tapered channel.

78. (New) An aerosolization system as in claim 69 wherein the flow regulator comprises a feedback mechanism.

79. (New) An aerosolization system as in claim 69 wherein the flow regulator regulates the flow through the airway at a rate less than 15 L/min.

80. (New) An aerosolization system as in claim 69 wherein the deagglomeration mechanism comprises a change in direction of the airway.

81. (New) An aerosolization system as in claim 69 wherein the deagglomeration mechanism comprises a constriction in the airway that causes an increase in flow rate therethrough.

82. (New) An aerosolization system as in claim 69 wherein the pharmaceutical formulation is a powdered medicament.

83. (New) An aerosolization system as in claim 82 wherein the powdered medicament comprises particles having a mass median diameter of less than 10  $\mu\text{m}$ .

84. (New) An aerosolization system as in claim 82 wherein the powdered medicament has a moisture content of less than 10% by weight.

85. (New) An aerosolization system as in claim 69 wherein the pharmaceutical formulation comprises insulin.

86. (New) An aerosolization system as in claim 69 wherein the mouthpiece comprises a tongue depressor.